# 510(k) Summary Pursuant to 21 CFR 807.92

## General Company Information

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|---|---|
| **Company Name:** | Normed® Medizin-Technik GmbH |
| **Company Address:** | Ulrichstrasse 7<br>D-78532<br>Tuttlingen, Germany |
| **Company Telephone:** | + (011) 49 7461 93 43 0<br>+ (011) 49 7461 93 43 20 |
| **Contact:** | David Furr, MS<br>FDC Services, LLC<br>US Agent |
| **Contact Address:** | 8708 Capehart Cove<br>Austin, Texas 78733<br>(512) 906-9654 |
| **Date:** | August 2, 2013 |
| **Device Trade Name:** | Normed® ANKLE FIX and ANKLE FIX + Systems 4.0 |
| **Common Name:** | bone plates and bone screws |
| **Classification Name and Reference:** | HRS- 888.3030, single/multiple component metallic bone fixation appliances and accessories<br><br>HWC-888.3040, Smooth or threaded, metallic bone fixation fastener |
| **Predicate Device:** | *Normed* Titanium Calcaneus Plating with Locking Screw System - K022324, cleared 9/17/02 |

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VLP Foot Talus and Percutaneous Calcaneus Bone Plates, VLP Bone Screws; Peri-Loc Ankle Fusion Bone Plates and Instruments – K110670, cleared 7/12/11

Ascension Ankle Fusion Plate System – K100176, cleared 6/16/10

**Device Description:**

The Normed ANKLE FIX and ANKLE FIX + Systems 4.0 are titanium plate and screw systems intended for internal fracture fixation of the ankle. The pre-contoured plates are anatomically designed for optimal screw positioning. This trauma system offers lateral plates for fusion of the tibio-talar (ANKLE FIX) and tibiotalo-calcaneal (ANGLE FIX +) bones as well as medial, posterior (hindfoot), posterior tibia and anterior plates as needed for the ankle for stability.

**Intended Use:**

The ANKLE FIX and ANKLE FIX + System 4.0 are intended to support normal bone healing for osteotomies, fractures and reconstruction.

The systems are indicated for:

- skeletal osteosynthesis of small bone fragments, which were damaged due to trauma or require reconstruction or arthrodesis
- primary or revision tibio-talar and tibiotalo-calcaneal fusion especially in the presence of osteopenic bone, hindfoot deformity and bone loss
- post-traumatic surgery.

**Testing and Technological Characteristics:**

The technological characteristics of this ankle system are similar to its predicates by having the similar intended use, material, lengths, thickness and overall design. The implants are provided sterile and non-sterile. They are for single use orthopaedic surgical application. The instruments are non-sterile and reusable.

Non-clinical testing demonstrated for the Normed ANKLE FIX and ANKLE FIX + Systems 4.0 meets performance requirements as defined by Design Control activities and are substantially equivalent to the predicate devices in terms of safety and efficacy.

| Device | Testing | Standard |
|---|---|---|
| **Plates** | Static and dynamic 4 point bending tests were performed on the worst case | ASTM 382-99 |
| **Screws** | Torsional properties, driving torque, and axial pull-out strength tests were performed on the worst case | ASTM F543-07 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

Normed® Medizin-Technik GmbH
% FDC Services, LLC
Mr. David C. Furr
Principle Consultant, US Agent
8708 Capehart Cove
Austin, Texas 78733

Re: K123347
Trade/Device Name: Normed® ANKLE FIX and ANKLE FIX PLUS Systems 4.0
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: June 18, 2013
Received: July 3, 2013

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number: K123347

Device Name: ANKLE FIX and ANKLE FIX Plus Systems 4.0

Indications For Use:

ANKLE FIX and ANKLE FIX + Systems 4.0 are indicated for:

- skeletal osteosynthesis of small bone fragments, which were damaged due to trauma or require reconstruction or arthrodesis
- primary or revision tibio-talar and tibiotalo-calcaneal fusion especially in the presence of osteopenic bone, hindfoot deformity and bone loss
- post-traumatic surgery.

Prescription Use X or Over-the-counter use
(per CFR 801.109)

Concurrence of CDRH

Elizabeth L. Frank -S

Division of Orthopedic Devices